K131085

Appendix 5-1

Mespere LIFE SCIENCES

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510(k) SUMMARY

Submitted by: Mespere LifeSciences Inc.
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AUG 2 2 2013

Company contact: Helen Tan, Vice President, Regulatory Affairs and Quality Assurance

Date summary prepared: 04/05/2013

Trade name: Central Venous Pressure System – Mespere Venus 1000

Common name: CVP System

Classification name: 870.1140 (Product code PFA)

Classification: Class II Medical Device

Predicate Device: K014054
EDWARDS LIFESCIENCES SWAN-GANZ MONITORING CATHETER WITH OLIGON MATERIAL
Product code: DQO
Regulation number: 870.1200

K120773
Nellcor Bedside SPO2 Patient Monitoring System
Product code: DQA
Regulation Number: 870.2700

K102968
Draeger Infinity CNAP SmartPod
Product Code: DXN
Regulation Number: 870.1130

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Device Description:

The Mespere LifeSciences Inc. Mespere Venus 1000 Central Venous Pressure System is used to indicate right heart pressure at the superior vena cava, which is clinically referred to as central venous pressure (CVP).

The main components of the Mespere Venus 1000 System include: a handheld display unit, a pressure sensor cable unit, neck patch adhesive liners, an adhesive reference patch, and a docking station for calibration and charging. The handheld unit displays the CVP value at a refresh rate of one second and the plethysmographic waveform.

The device is intended for use in hospital and clinical environments by healthcare professionals.

Intended Use/Indications For Use:

The Venus 1000 System is intended to be used by healthcare professionals for assessment of central venous blood pressure (CVP) of adult individuals.

Technology Characteristics:

The Venus 1000 System and the predicate device - Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon Material have the same intended use with respect to measuring right heart pressures. However, they have different technology characteristics. The Venus 1000 System is based on non-invasive near infrared spectroscopy (NIRS) technology. The Edwards Lifesciences Swan-Ganz Monitoring Catheter is based on invasive catheter and pressure transducer technology. The Venus 1000 System is safer and easier to use than catheters for right heart pressure measurement.

The Venus 1000 system and the predicate devices - Nellcor Bedside SPO2 Patient Monitoring System and the Draeger Infinity CNAP SmartPod have the similar technology. They all based on non-invasive near infrared spectroscopy (NIRS). The Venus 1000 System uses single-wavelength LEDs and photodetectors (PD) to detect changes in blood volume. The Nellcor Bedside SPO2 Patient Monitoring System uses multiple wavelength LEDs and photodetectors to detect ratio of light absorption between oxygenated and deoxygenated haemoglobin. The Draeger Infinity CNAP SmartPod uses photoplethysmograph sensors (LEDs and detectors) to detect changes in blood volume.

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Complied Standards:

The design of the Mespere Venus 1000 device conforms to the following voluntary standards:

- IEC 60601-1: 2005 - edition 3.0
- IEC 60601-1-2: 2007 - edition 3.0
- IEC 60601-1-4: 2000
- IEC 60601-1-6: 2010
- IEC/ISO 62366:2007
- ISO 14971:2007
- ISO 14155:2011
- IEC/EN 62304:2006
- EN 980:2008
- EN 1041:2008
- ISO 15223-1:2012
- ISO 13485:2003
- ISO 10993-1:2009
- ISO 2859-1:1999

Non-Clinical Tests:

The Venus 1000 System was subjected to extensive safety testing, performance testing, and verification testing. Tests of the Venus 1000 System included various performance tests and software tests, designed to ensure that the device met all its functional specifications. A bench test verified the performance of the device to meet the design requirements in an ideal non-clinical environment. All tests were performed to ensure the device complies with industry and safety standards.

Clinical Tests:

Clinical tests were performed to verify and validate the clinical performance of the Venus 1000 System and support the determination of substantial equivalence. The following clinical data was submitted:

Clinical verification: The primary objective of this study was to investigate the usability, accuracy and correlation of Mespere Venus 1000 System for measuring central venous pressure, by comparing it to physical examination of CVP obtained by physicians. The subjects recruited for this study were a mix of healthy volunteers and patients.

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Results: The clinical verification demonstrated the claimed accuracy and appropriate usability of the Mespere Venus 1000 System for measuring CVP.

No adverse events were reported.

Clinical Validation: The primary objective of this study was to validate the accuracy of central venous pressure (CVP) readings of the Venus 1000 System by comparison to the Edwards Swan-Ganz right heart catheter (RHC). The recruited subjects consisted of acute and chronic heart failure patients already receiving RHC as part of their usual care. RHC was performed in the standard fashion.

Results: The clinical validation study demonstrated that the Mespere Venus 1000 System is equivalent in performance to the Edwards Lifesciences Swan-Ganz catheter with respect to measuring CVP.

No adverse events were reported.

Substantial Equivalence of Performance:

The Venus 1000 device is substantially equivalent to the predicate devices in terms of the performance and the technology safety and effectiveness.

Conclusions:

The conclusions drawn from the above performance and clinical testing is that the Mespere Venus 1000 CVP System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 22, 2013

Mespere LifeSciences Inc
C/O Helen Tan
180 Frobisher Dr. Unit 1C
Waterloo, ON, CA N2V2A2

Re: K131085
Trade/Device Name: Central Venous Pressure System
Regulation Number: 21 CFR 870.1140
Regulation Name: Venous Blood Pressure
Regulatory Class: Class II
Product Code: PFA
Dated: June 28, 2013
Received: July 16, 2013

Dear Helen Tan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known):

Device Name: Central Venous Pressure System

Indications For Use: Mespere Venus 1000 is intended to be used by healthcare professionals for assessment of central venous blood pressure (CVP) of adult individuals.

Prescription Use _Yes____ AND/OR Over-The-Counter Use ___No____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.08.22
15:40:41 -04'00'